



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 10/666,168
Filing Date: September 19, 2003
Applicant: Phillip Martin Gibbs et al.
Group Art Unit: 3738
Examiner: Bruce E. Snow
Title: MODULAR PROSTHETIC HEAD HAVING A FLAT
PORTION TO BE IMPLANTED INTO A CONSTRAINED
LINER
Attorney Docket: 5490-000301

Director of the United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 C.F.R. § 1.131

Sir:

We hereby declare under penalty of perjury as follows:

1. We are the inventors of the claimed subject matter of the subject patent application.
2. Exhibit A is a page from an engineering notebook that is dated and witnessed, with dates redacted, prior to January 3, 2002.
3. Before January 3, 2002, we conceived of and/or reduced to practice in the United States, a prosthesis system for implantation into an anatomy that includes a ball portion and a cup portion with an entrance. The ball portion has a portion with a dimension equal to or less than a dimension of the entrance to the cup portion. The ball

portion also has a portion with a dimension greater than a dimension of a concave area, as evidence by the following.

4. The page in Exhibit A is entitled "Constrained Liner Idea" that illustrates, in the upper left-hand corner thereof, a liner with a ring that would interact with the liner and it is stated in Exhibit A a "liner that fits ordinary shells with ring that is installed at Biomet".

5. The page in Exhibit A also states that "the endo type head would have a small flat around the equator to allow it to go into the liner. The flat could be positioned in a way that the head would be unlikely to dislocate, but in a position that would allow a surgeon to position the leg to reduce the hip in surgery". This concept is further illustrated in the lower right-hand corner of the page as an exemplary head illustrated with a flat portion thereon.

6. Exhibit B is a R&D Work Request, with date information redacted that is evidence that parts were made by us or on our orders and delivered to us on or before January 3, 2002.

7. Exhibit B includes drawing prints showing configurations and dimensions of various head portions for a femoral head replacement that includes a reduced radius or "flat" portion.

8. Exhibit C is an "Investigational" router, with date information redacted, that illustrates a design of a liner that can include a ring positioned near an opening into an interior portion of the liner. Exhibit C includes a redacted start date before January 3, 2002 (on the first page) and a completion date of January 3, 2002 (shown as the date of "Inspect" on the last page of the "Investigation").

9. The liner illustrated in Exhibit C would allow, and was made for, insertion of a head portion, as illustrated in Exhibit B, to enter the interior portion of the liner when an axis of a the reduced radius area is aligned with an axis of the entrance.

10. Exhibit D is an Applied Technology Mechanical Test Request Form and accompanying drawings and test data, with proprietary data redacted. Exhibit D includes a Requested by W. J. Slone and a Date Submitted of January 3, 2002 and a Test Close-Out Information that illustrates that the requested tests were Conducted by K. Howard and Dated Completed was January 7, 2002.

11. Exhibit D includes a cover sheet that describes that two sets of liners, one with a Cobalt reinforcement ring and one with a titanium reinforcement ring were used with three different types of femoral heads in a lever-out test. The three heads were a 36mm full spherical, a 36mm full spherical with a 34.5 mm circumferential flat, and a 36mm full spherical with a 35.0 mm circumferential flat.

13. Exhibit D also illustrates that the various samples, Sample 4, Sample 5, Sample 12, Sample 13, Sample 6, Sample 7, Sample 14, and Sample 15, that clearly include the circumferential flats in a starting position and In a maximum load position relative to a liner that includes a constraining ring.


14. Exhibit A, with dates redacted illustrates a conception and/or reduction to practice of the subject matter of the claims in the subject application. Exhibits B and C provide evidence that the subject matter of the claims in the present application was reduced to practice and built on or before January 3, 2002. Finally, Exhibit D is evidence that parts embodying the subject matter of the claims of the present invention were tested on or before January 7, 2002

15. We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are being made with the knowledge that willful false statements and the like so made are punishable by fine or Imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, and patent issuing thereon, or any patent to which this verified statement is directed.

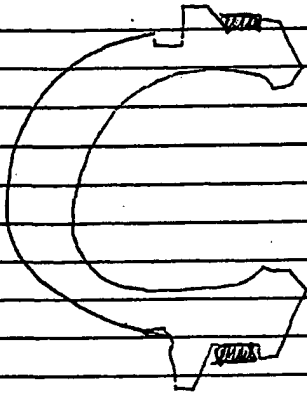
Dated: 3-28-06


Phillip Martin Gibbs

Dated: 3-28-2006


William Jason Slone

CONSTRAINED LINER IDEA



LINER THAT FITS ORDINARY
SHELLS WITH RING THAT
IS INSTALLED AT 60 MET

(NO SLITS)

LIKE JASON SLOWE'S
IDEA. ~~SHRINK THE CUP BY~~

MIGHT EVEN BE ABLE TO
SHRINK POLY IN COLD ENVIRONMENT / WARM RING
TO ~~INSTALL~~ ASSEMBLE
AND/OR

SURGEON INSTALLS THIS LINER IN CUP

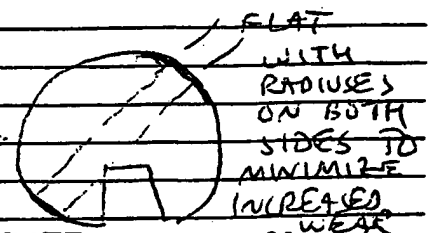
WOULD HAVE LARGE ENOUGH I.D. TO

OFFER GOOD RANGE OF MOTION WITH TYPE
ONE TAPER.

OFFER VARIOUS NECK LENGTH ENDO TYPE
HEADS TO MATE WITH I.D. OF LINER

THE REALLY UNIQUE THING HERE IS THAT
THE ENDO TYPE HEAD WOULD HAVE A SMALL
FLAT AROUND THE EQUATOR TO ALLOW IT TO
GO INTO THE LINER. THE FLAT COULD BE
POSITIONED IN A WAY THAT THE HEAD WOULD
BE UNLIKELY TO DISLOCATE, ~~IN OTHER WORDS~~
~~IT WOULD BE IMPOSSIBLE TO~~ BUT IN A POSITION
THAT WOULD ALLOW THE SURGEON TO POSITION THE
LEG TO REDUCE THE HIP IN SURGERY

NOTE FULL SPHERE
AS MUCH AS POSSIBLE
NO FLAT ☒ YES ☐ NO



SIGNATURE _____

READ AND UNDERSTOOD William V. Stone

DATE _____

DATE _____

20

20



R&D WORK REQUEST

Request Date: [REDACTED]

Engineer: Phil Gibbs
Project Number:

ext. 1690

Product Name: modular heads with flats

Make Per:

☒ Print (Attached)
☐ CAD Data File

18399i.tif 18399b.tif 18399c.tif
18399d.tif 18399e.tif 18399f.tif
18399g.tif 18399h.tif 18399i.tif
18399j.tif 18399k.tif 18399a.tif

Using:

Qty: 6

☒ Material On-Hand
☐ Material Provided
☐ Parts Provided

Bill To:

☐ Distributor
☒ Departmental Charge

Price Quoted

Time and Materials:

Instructions:

this research was originated to support constrained liner development. by decreasing ROM slightly, we should be able to experience much greater pull-out and lever-out and still be able to assemble. question is increased wear concerns

Shop Log				
Date	Hrs	Name	Notes From Shop	
	6.00	Monty Lackey		
	10.00	Don DeCook		
	8.00	Monty Lackey		
	8.00	Monty Lackey		
			Traceable Materials	
			Material	Lot #

Vendor No:

Engineering Information

P.O. No:

Req. No:

Comp. Date: [REDACTED]

Completed Documents:


Department:	Hips	Other:
Classification:	R&D	
Total Hours:	32.00	
Order No.: 18399		

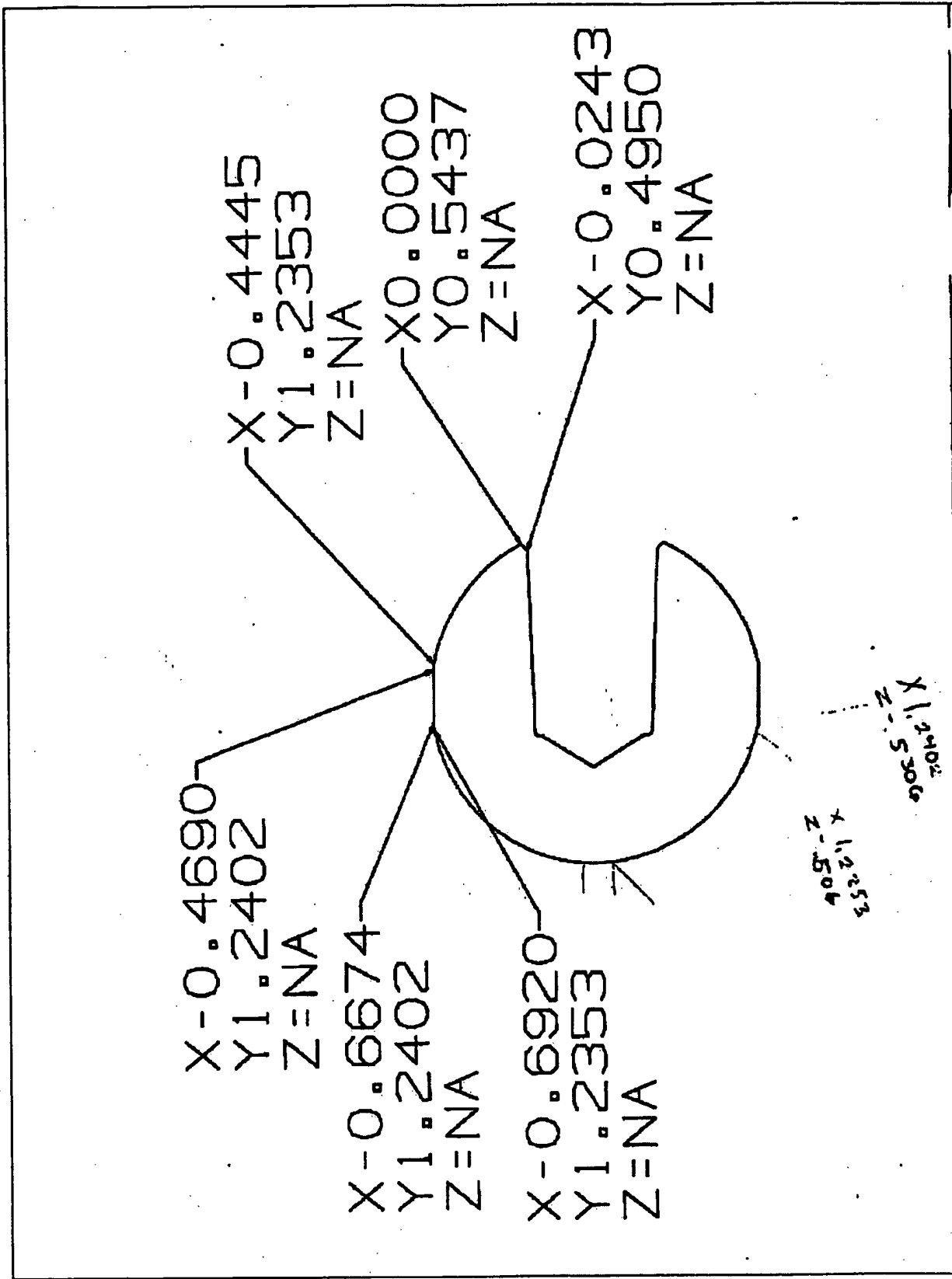
AMAZON: NEW LOT NO AND

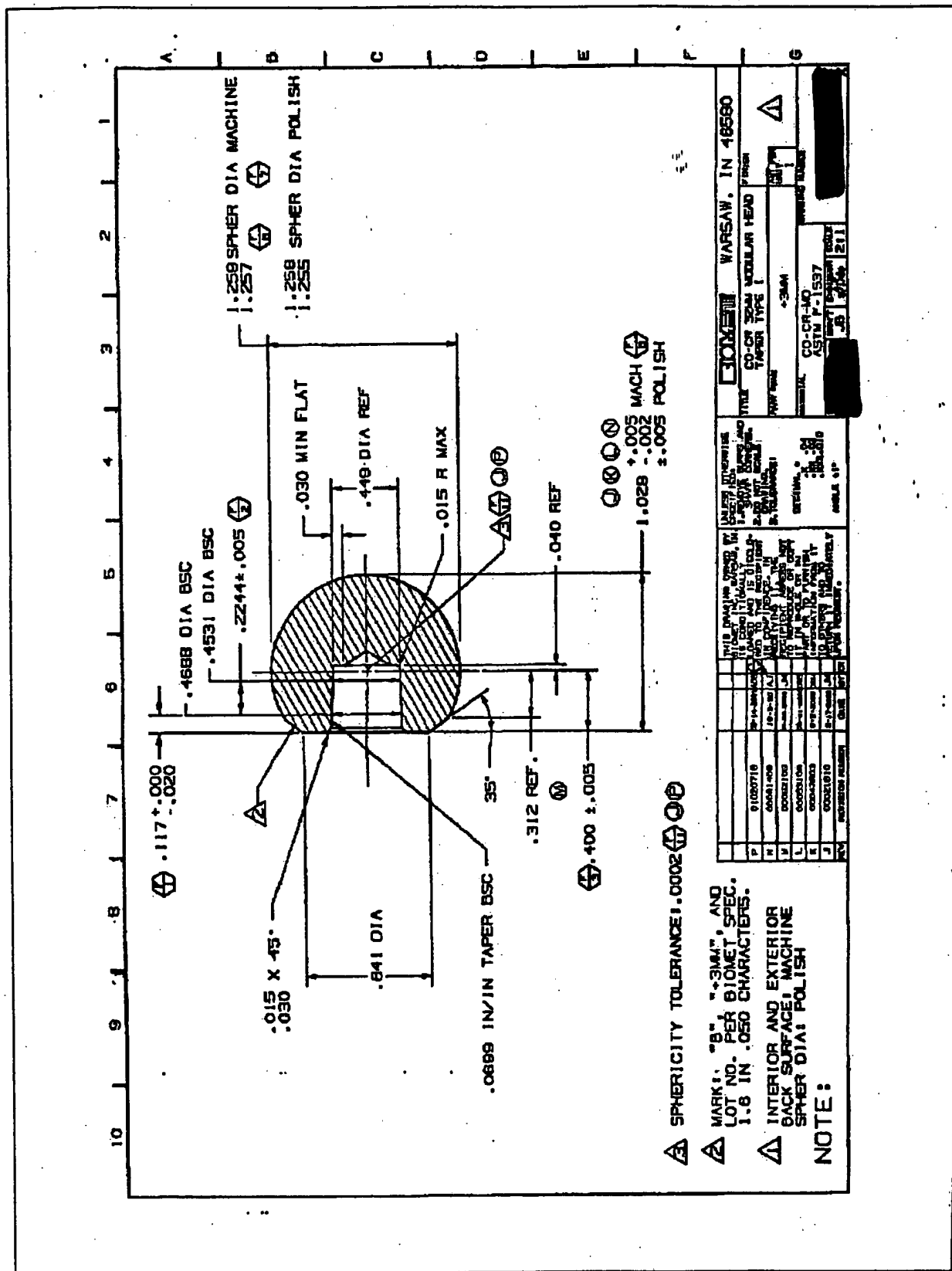
MARK: "B", LOT NO. AND
"STD" PER BIOMET
SPEC. 1.8.

**△ INTERIOR AND EXTERIOR
BACK SURFACE: MACHINE
SPHERE-R: POLISH.**

NOTE:

TITLE CO-OR 2304 MODULAR HEAD TAPER TYPE J. METAL ON METAL PART NAME STD 2/31.5MM FLAT PART NUMBER 1		FINISH SEE NOTES 	
MATERIAL Co-Or-MG PER ASTM F-75		DRAWN BY J. SWINNEY DATE 11/1/80 CHECKED BY J. SWINNEY DATE 11/1/80	
QUANTITY 211		XXXXXX	





PAGE: 49

TIME: 21:11

DATE: [REDACTED]

C A R L Z E I S S Measurement system

No. TASK	REM	BY	ACTUAL	NOMINAL	UPPERTOL	LOWERTOL	DEVIATION	OVER
----------	-----	----	--------	---------	----------	----------	-----------	------

4. VALID: SPHERICAL SPHERIC LITIGATION

1 SPHERE	Z		.57883					
	R		.77302					
	SD		.00173					

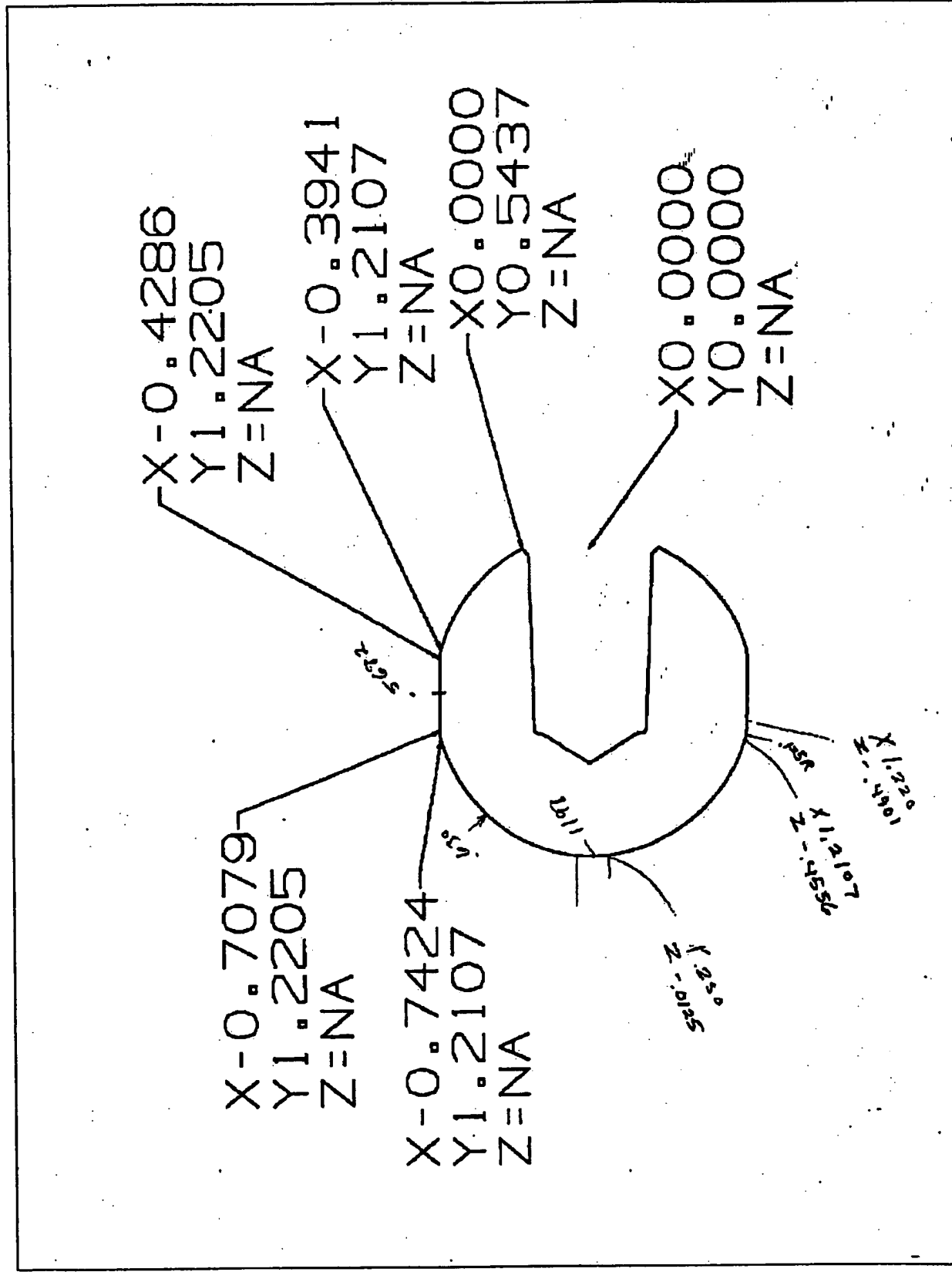
PAGE: <3

TIME: 0:14

DATE: [REDACTED]

C A K L Z E I S S Measurement system

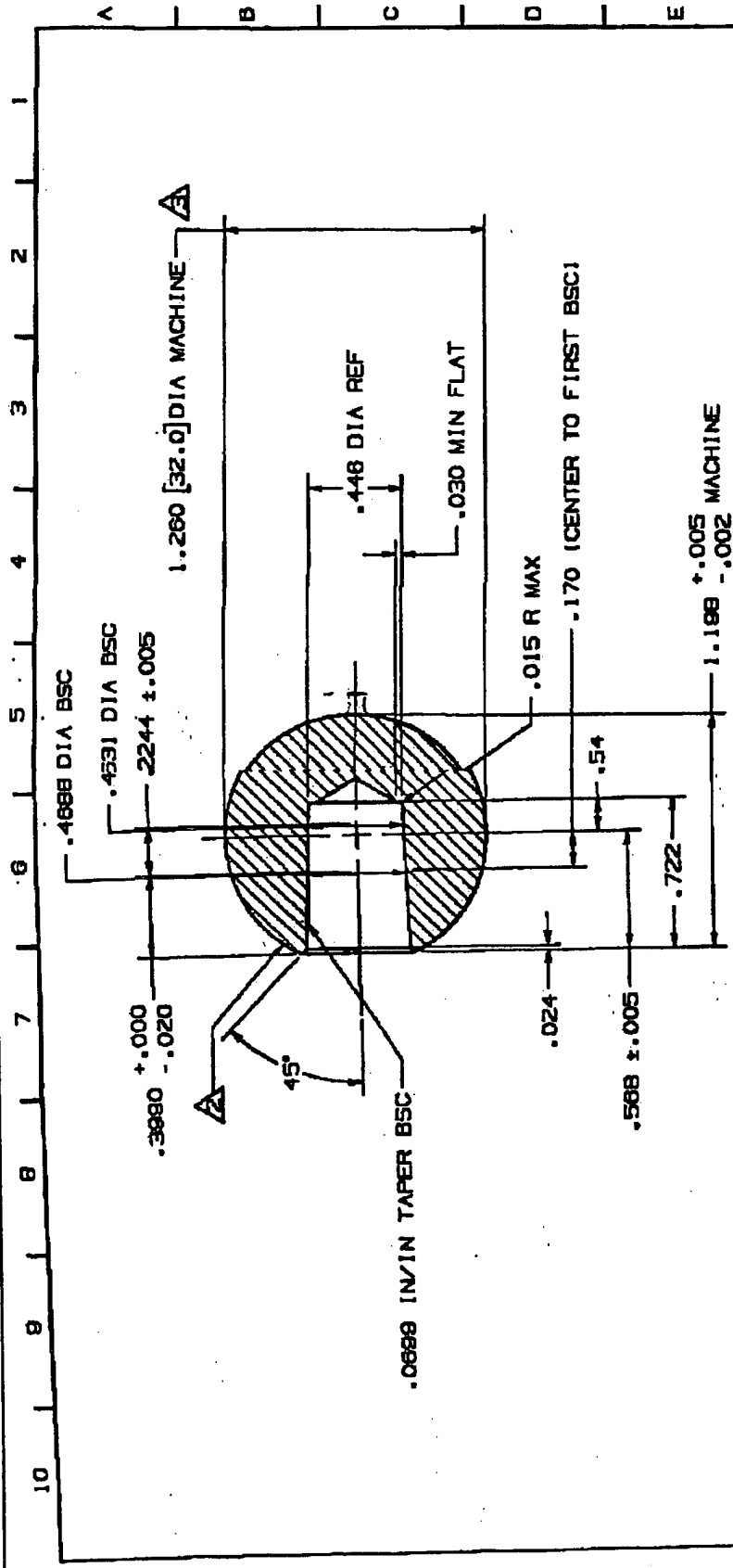
No.	TASK	KEM	SY	ACTUAL	NOMINAL	UPPER TOL	LOWER TOL	DEVIATION	OVER
Z VALUE EQUALS SPHERE LOCATION									
1	SPHERE		Z	.60395					
			R	.71043					
			Rd	.00029					



NOTE:

mdum\PG\bb\HEADS w-Flats\32mm Std Head w31mm Flat.prb

[illegible]



INDUSTRY PRACTICES
HEADS w-Flats
32mm Std Head w/No Flat.prt F

WARSZAWA, IN 46580

Co-Cr-Mo
PER ASTM F-75

XXXXXX

NOTE: INTERIOR AND EXTERIOR BACK SURFACE: MACHINE SPHERE R: POLISH.

MARK: "B", LOT NO. AND "STD" PER BIONET SPEC. 1.6.

SPHERICITY TOLERANCE: $\pm .0002$ IN (25 MICRONS).

NO.	REVISION	DATE	BY
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			

CHECKS VERIFICATION	DATE	BY
1. REMOVE FLAPS		
2. REMOVE FLAPS		
3. TOLERANCES		
4. TOLERANCES		
5. TOLERANCES		
6. TOLERANCES		
7. TOLERANCES		
8. TOLERANCES		
9. TOLERANCES		
10. TOLERANCES		

THIS DRAWING IS THE PROPERTY OF THE COMPANY. IT IS TO BE USED ONLY FOR THE PURPOSES FOR WHICH IT WAS DESIGNED. IT IS NOT TO BE REPRODUCED OR TRANSMITTED IN ANY FORM OR BY ANY MEANS, ELECTRONIC OR MECHANICAL, WITHOUT THE WRITTEN PERMISSION OF THE COMPANY.

THIS CHECKING ORDER BY BICENT INC., A
BANK, IS CONDITIONALLY LOANED AND IS OBLIGED TO THE RECIPIENT IN ORDER TO
ON DATE OF THE DAY OF PAYMENT TO THE RECIPIENT AND TO RETURN IT TO THE RECIPIENT.

		CHECKS AFFILIATIONS	ALLIES OR ENEMIES	COMINT	WARSAW, IN 4B580
		DRAFTING	DATE		
				TITLE	CO-CR 39MM MODULAR HEAD SEE
					PARTIALS

[illegible]

PER ASIM F-75	DATE	ENFT	POINTECH	SCALE
		M/D	P-G	211
XXXXXX				

[illegible]

SPHERICITY TOLERANCE: $\pm .0002$ IN (.5 MICRONS).

MARK: "B". LOT NO. AND
"STD" PER BIOMET
SPEC. 1.6.

**△ INTERIOR AND EXTERIOR
BACK SURFACE: MACHINE
SPHERE R: POLISH.**

NOTE:

[illegible]

NOTE:

[illegible]



R&D WORK REQUEST

Request Date: [REDACTED]

Engineer: Phil Gibbs

ext. 1690

Project Number:

Product Name: modular heads with flats

Make Pen

☒ Plans (Attached)

☐ CAD Data File

Using

☒ Material On Hand

☐ Material Provided

☐ Parts Provided

Qty: 6

Bill To: ☐ Distributor

☒ Departmental Charge

Price Quoted

Time and Materials:

NEEDS ASAP

Instructions:

this research was originated to support constrained knee development. by decreasing ROM slightly, we should be able to experience much greater pull-out and lever-out and still be able to assemble. question is increased wear concerns

Shop Log					
Date	Hr's	Name	Notes From Shop		
[REDACTED]	6	Monty			
[REDACTED]	10	Dulok			
[REDACTED]	8	Monty			
[REDACTED]	8	Monty			
			Traceable Materials		
			Material	Lot#	Location
			01-02-0014A	990932	the cage

Vendor No:

P.O. No:

Req. No:

Comp. Date: Complete

Completed Documents:

Engineering Information		
Department:	Hips	Other:
Classification:		
Total Hours:	0.00	
Order No.: 18399		

ENTERED

ATTACH SAMPLE LABEL HERE:



LOT 815390

**LOT 815390**

QTY. 1

BOMET ORTHOPEDICS, INC.
65 EAST FIELD DRIVE
P.O. BOX 687
WARHAW, IN 46581 USA

STERILE
2002-01

COMPONENT	ITEM	DESCRIPTION	U/M	TYPE	QTY.	RECD	OPER
-----------	------	-------------	-----	------	------	------	------

WORK	OP.	IN	RD	ARCOM	UHMWPE	IN	2	95-00
01-07-0422	755840	2.000						40'12
	728010							+54
	755830							+27
	728000							27
	728000							+18'2
	755810							+18'2

WORK CENTER	OF. SBO.	OPERATION DESCRIPTION	TOOL NUMBER	PROCESS NUMBER	LABEL COLOR

10408 0020 CUT BLANK



•TN6120961

[illegible]

WORK CENTER	OP. SEQ.	OPERATION DESCRIPTION	PCS. PER TOOL HOUR	PROCESS NUMBER	LABEL COLOR
28010	0040	TRUN O.D.	5.00		



• TN6120999

[illegible]

28000	0060	MILL SCALLOPS	VR0207	5.00
-------	------	---------------	--------	------



.TN6121005

[illegible]

28010 0080 BORE I.D. *LB4603* 5.00



•TN6121013

[illegible]

101

CURRENT DATE:

PAGE: 3

FINISHED ITEM	DESCRIPTION	START DTE	JOB NO.	ORDER QTY	PLNR
INVESTIGATIONAL CONST.	TRI-POLAR	0/00/00	0000000	20.000	88

[illegible]

10.00

Return to Gregg Porter

Ext. 1852

- 7N6321021

[illegible]

38.61

1 ETCH "SAMPLE" ON O.D. RADIUS

-TN6121039

[illegible]

33.33

SEE TIMMY RHODES
FBI 1-3-02

• TN6323047

[illegible]

MB15390 ENTRY
 FINISHED
 INVT

TIMES PRINTED: MM
 CURRENT DATE: XXXXXXXXXX PAGE: 4
 START DTE 00000000 ORDER QTY 20.000 PLNR 88
 0/00/00 0000000 20.000 88

PCB. PER TOOL PROCESS LABEL
 TION HOUR NUMBER NUMBER COLOR

"RUSH"
 SHIP SEULE FLI.
 1-4-02

50.00



.TN6121054

TV Tammy

DATE	AP	INSPECT	CLOCK	REWORK
1-3	TSR	ACC	REJ	S/L

12116 0180 PACKAGE STERILE 33.33



.TN6121062

DATE	CLOCK	OPER.	PIECES	SCRAP	INSPECT	CLOCK	REWORK
	NUMBER	NUMBER	PROD.	PIECES	ACC	REJ	PIECES
1-3	4476	180	16				

12118 0200 LABEL & BOX 30.03 LOGO

SEE TAMMY @ HANCOCK
 732 1-5-02



.TN6121070

1 RETURN TO GREGG PORTER EXT 1852

DATE	CLOCK	OPER.	PIECES	SCRAP	INSPECT	CLOCK	REWORK
	NUMBER	NUMBER	PROD.	PIECES	ACC	REJ	PIECES
1-3	4789	200	16				
1-3							
1-3							

MR.

PAGE: 5

0/00/00 00000000

20.000 88

PCS. PER TOOL PROCESS

83.33



DATE 7-3

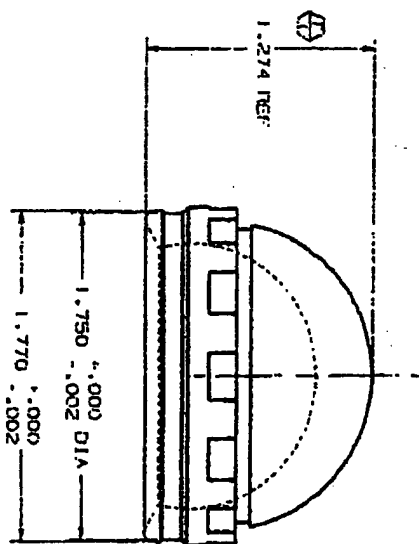
-TN6121096

DATE

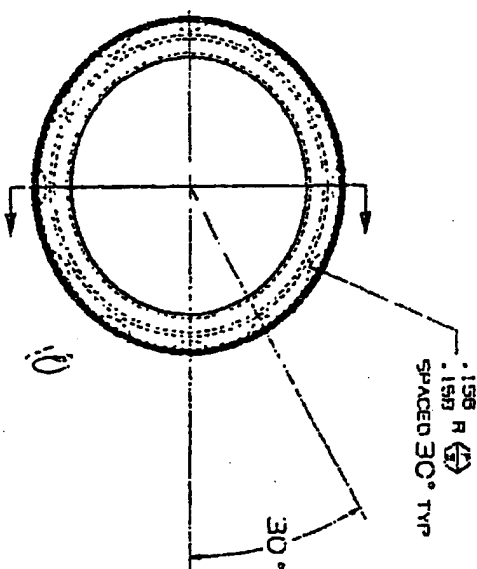
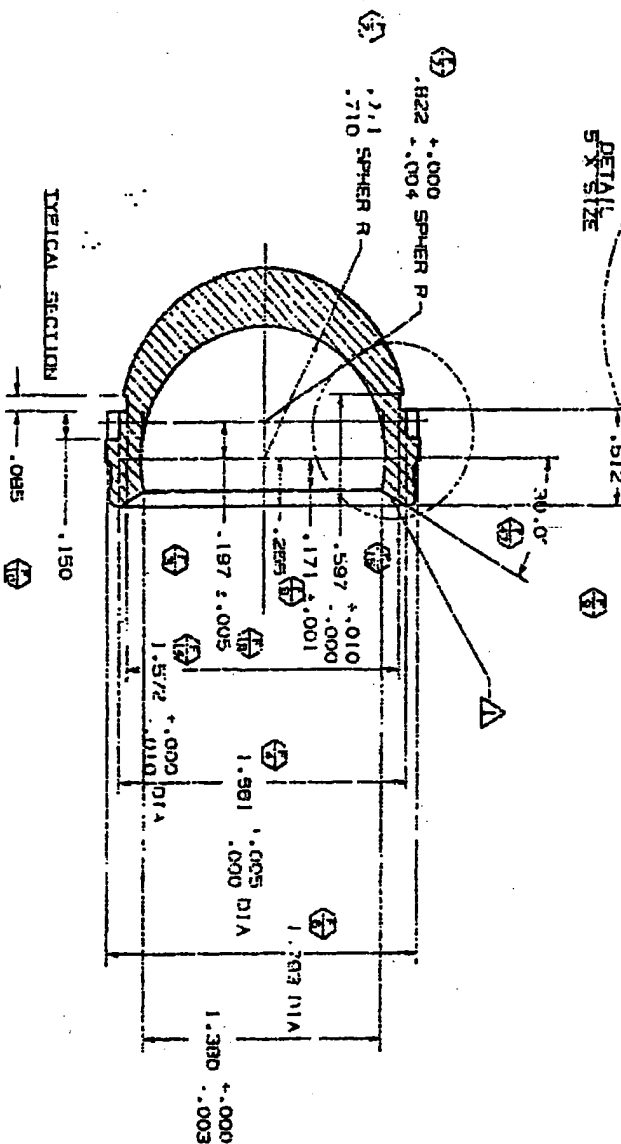
NUMBER
240

PROJ. 16

PIECE
0



DETAILED
SYNOPSIS



THEORETICAL SECTION

MARK, "B" LOT NO., AND "PROTOTYPE" (SIZE, PER BIOMET SPEC. 1.8).
EXAMPLE: B XXXXX "PROTOTYPE"

NOTE:

1. NAME OF THE PARTY OR PERSON 2. ADDRESS 3. CITY 4. STATE 5. ZIP CODE 6. COUNTRY		7. TYPE OF PARTY OR PERSON 8. DATE OF BIRTH 9. DATE OF DEATH 10. DATE OF ARRIVAL 11. DATE OF DEPARTURE		12. TYPE OF VEHICLE 13. MAKE 14. MODEL 15. YEAR 16. COLOR 17. LICENSE NUMBER 18. REGISTRATION STATE		19. TYPE OF VEHICLE 20. MAKE 21. MODEL 22. YEAR 23. COLOR 24. LICENSE NUMBER 25. REGISTRATION STATE		26. TYPE OF VEHICLE 27. MAKE 28. MODEL 29. YEAR 30. COLOR 31. LICENSE NUMBER 32. REGISTRATION STATE		33. TYPE OF VEHICLE 34. MAKE 35. MODEL 36. YEAR 37. COLOR 38. LICENSE NUMBER 39. REGISTRATION STATE		40. TYPE OF VEHICLE 41. MAKE 42. MODEL 43. YEAR 44. COLOR 45. LICENSE NUMBER 46. REGISTRATION STATE		47. TYPE OF VEHICLE 48. MAKE 49. MODEL 50. YEAR 51. COLOR 52. LICENSE NUMBER 53. REGISTRATION STATE		54. TYPE OF VEHICLE 55. MAKE 56. MODEL 57. YEAR 58. COLOR 59. LICENSE NUMBER 60. REGISTRATION STATE		61. TYPE OF VEHICLE 62. MAKE 63. MODEL 64. YEAR 65. COLOR 66. LICENSE NUMBER 67. REGISTRATION STATE		68. TYPE OF VEHICLE 69. MAKE 70. MODEL 71. YEAR 72. COLOR 73. LICENSE NUMBER 74. REGISTRATION STATE		75. TYPE OF VEHICLE 76. MAKE 77. MODEL 78. YEAR 79. COLOR 80. LICENSE NUMBER 81. REGISTRATION STATE		82. TYPE OF VEHICLE 83. MAKE 84. MODEL 85. YEAR 86. COLOR 87. LICENSE NUMBER 88. REGISTRATION STATE		89. TYPE OF VEHICLE 90. MAKE 91. MODEL 92. YEAR 93. COLOR 94. LICENSE NUMBER 95. REGISTRATION STATE		96. TYPE OF VEHICLE 97. MAKE 98. MODEL 99. YEAR 100. COLOR 101. LICENSE NUMBER 102. REGISTRATION STATE		103. TYPE OF VEHICLE 104. MAKE 105. MODEL 106. YEAR 107. COLOR 108. LICENSE NUMBER 109. REGISTRATION STATE		110. TYPE OF VEHICLE 111. MAKE 112. MODEL 113. YEAR 114. COLOR 115. LICENSE NUMBER 116. REGISTRATION STATE		117. TYPE OF VEHICLE 118. MAKE 119. MODEL 120. YEAR 121. COLOR 122. LICENSE NUMBER 123. REGISTRATION STATE		124. TYPE OF VEHICLE 125. MAKE 126. MODEL 127. YEAR 128. COLOR 129. LICENSE NUMBER 130. REGISTRATION STATE		131. TYPE OF VEHICLE 132. MAKE 133. MODEL 134. YEAR 135. COLOR 136. LICENSE NUMBER 137. REGISTRATION STATE		138. TYPE OF VEHICLE 139. MAKE 140. MODEL 141. YEAR 142. COLOR 143. LICENSE NUMBER 144. REGISTRATION STATE		145. TYPE OF VEHICLE 146. MAKE 147. MODEL 148. YEAR 149. COLOR 150. LICENSE NUMBER 151. REGISTRATION STATE		152. TYPE OF VEHICLE 153. MAKE 154. MODEL 155. YEAR 156. COLOR 157. LICENSE NUMBER 158. REGISTRATION STATE		159. TYPE OF VEHICLE 160. MAKE 161. MODEL 162. YEAR 163. COLOR 164. LICENSE NUMBER 165. REGISTRATION STATE		166. TYPE OF VEHICLE 167. MAKE 168. MODEL 169. YEAR 170. COLOR 171. LICENSE NUMBER 172. REGISTRATION STATE		173. TYPE OF VEHICLE 174. MAKE 175. MODEL 176. YEAR 177. COLOR 178. LICENSE NUMBER 179. REGISTRATION STATE		180. TYPE OF VEHICLE 181. MAKE 182. MODEL 183. YEAR 184. COLOR 185. LICENSE NUMBER 186. REGISTRATION STATE		187. TYPE OF VEHICLE 188. MAKE 189. MODEL 190. YEAR 191. COLOR 192. LICENSE NUMBER 193. REGISTRATION STATE		194. TYPE OF VEHICLE 195. MAKE 196. MODEL 197. YEAR 198. COLOR 199. LICENSE NUMBER 200. REGISTRATION STATE		201. TYPE OF VEHICLE 202. MAKE 203. MODEL 204. YEAR 205. COLOR 206. LICENSE NUMBER 207. REGISTRATION STATE		208. TYPE OF VEHICLE 209. MAKE 210. MODEL 211. YEAR 212. COLOR 213. LICENSE NUMBER 214. REGISTRATION STATE		215. TYPE OF VEHICLE 216. MAKE 217. MODEL 218. YEAR 219. COLOR 220. LICENSE NUMBER 221. REGISTRATION STATE		222. TYPE OF VEHICLE 223. MAKE 224. MODEL 225. YEAR 226. COLOR 227. LICENSE NUMBER 228. REGISTRATION STATE		229. TYPE OF VEHICLE 230. MAKE 231. MODEL 232. YEAR 233. COLOR 234. LICENSE NUMBER 235. REGISTRATION STATE		236. TYPE OF VEHICLE 237. MAKE 238. MODEL 239. YEAR 240. COLOR 241. LICENSE NUMBER 242. REGISTRATION STATE		243. TYPE OF VEHICLE 244. MAKE 245. MODEL 246. YEAR 247. COLOR 248. LICENSE NUMBER 249. REGISTRATION STATE		250. TYPE OF VEHICLE 251. MAKE 252. MODEL 253. YEAR 254. COLOR 255. LICENSE NUMBER 256. REGISTRATION STATE		257. TYPE OF VEHICLE 258. MAKE 259. MODEL 260. YEAR 261. COLOR 262. LICENSE NUMBER 263. REGISTRATION STATE		264. TYPE OF VEHICLE 265. MAKE 266. MODEL 267. YEAR 268. COLOR 269. LICENSE NUMBER 270. REGISTRATION STATE		271. TYPE OF VEHICLE 272. MAKE 273. MODEL 274. YEAR 275. COLOR 276. LICENSE NUMBER 277. REGISTRATION STATE		278. TYPE OF VEHICLE 279. MAKE 280. MODEL 281. YEAR 282. COLOR 283. LICENSE NUMBER 284. REGISTRATION STATE		285. TYPE OF VEHICLE 286. MAKE 287. MODEL 288. YEAR 289. COLOR 290. LICENSE NUMBER 291. REGISTRATION STATE		292. TYPE OF VEHICLE 293. MAKE 294. MODEL 295. YEAR 296. COLOR 297. LICENSE NUMBER 298. REGISTRATION STATE		299. TYPE OF VEHICLE 300. MAKE 301. MODEL 302. YEAR 303. COLOR 304. LICENSE NUMBER 305. REGISTRATION STATE		306. TYPE OF VEHICLE 307. MAKE 308. MODEL 309. YEAR 310. COLOR 311. LICENSE NUMBER 312. REGISTRATION STATE		313. TYPE OF VEHICLE 314. MAKE 315. MODEL 316. YEAR 317. COLOR 318. LICENSE NUMBER 319. REGISTRATION STATE		320. TYPE OF VEHICLE 321. MAKE 322. MODEL 323. YEAR 324. COLOR 325. LICENSE NUMBER 326. REGISTRATION STATE		327. 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Applied Technology Mechanical Test Request Form

Project : Constrained Liner II

Project #: HP000180

Title: Lever-out with 3 different 36mm Co-Cr Modular Heads

Test Type: ☐ Fatigue ☒ Static ☐ Rotating Beam ☐ Wear
☐ Other (specify) _____

Conducted: ☒ In-House
☐ Outside Lab (specify) _____

Test Components: (Part A is primary component for test)

	Part Name	Part #	Lot #	Size	Qty
A	23 Constrained +5 Liner w/Cobalt Ring	Investigational	815390	23	6
B	23 Constrained +5 Liner w/Cobalt Ring	Investigational	815390	23	6
C	36mm Fully-spherical Modular Head	Investigational		36mm	1
D	36/34.5mm Fully-spherical Modular Head with 34.5mm circumfrenclal flat	Investigational		36mm	1
E	36/35.0mm Fully-spherical Modular Head with 35.0mm flat	Investigational		36mm	1

If the test components are not finished production parts, please state why.

Material: A B C D E A B C D E
 X Ti-6Al-4V Stainless Steel (type) _____
 . X X X X CoCr X X UHMWPE
 P85/15 LactoSorb
 P82/18 Other (specify) _____
 Ceramic (specify) _____

Processing: (Check all that apply for each test component)

A B C D E	A B C D E	A B C D E
X X X Wrought	Forged	Cast
Molded	X X X X X Machined	X X X X X Passivated
Welded	Heat Treated (specify)	X X Packaged
Shot Peened Intensity	Blasted (# _____)	HA Coated
Ion Implanted	X X Ceramic Bead Blast	Full Plasma Spray
TiN Coated	X X X Laser Etched	MacroBond P Spray
Chem Etched	X X Sterilized (gamma)	Plasma Nitrided
Finished Goods (Lot#) X X X X X	Cleaned (powerwash/alcohol)	Other _____
Wire EDM'D	X X X Honed	X X X Polished

Specify differences between multiple specimens: The only difference between the two liners is the constraining ring. The liners themselves are from the same lot.

Objective(s) of Test: Determine the amount of torque required to lever-out three different 36.0 mm modular head designs from the liner, as well as determining how much if any a Cobalt Reinforcement ring will strengthen design from a Titanium Reinforcement Ring.

Test Procedure # See attached page (Outline the desired procedure if not a standard procedure).

Test Specifications: _____

Deviations from Standard: _____

Data to be Collected: ☒ Load vs. Deflection
☒ Max. Load
☐ Weight Loss

☐ # of Cycles to Failure
☒ Max. Deflection
☐ Other _____

Special Instructions: _____

Requestor to be present when test is started? ☒ Yes ☐ No

Requested By: W. F. Stone Date Submitted: 1/3/2002

Test Close-Out Information:

Conducted By: K. Howard Date Completed: 1-7-2002

Lab Book Reference: S-24 pg. 23

Test Specimen Disposition: ☒ Archived ☐ Returned To Engineer ☐ Discarded

Requestor Comments:

Requestor: W. F. Stone Date: 1/14/2002

Lab Supervisor:

Date:

Blomet Mechanical Test Lab
Static Test Data Sheet

Test # MT2439 Date Test Started 1-7-2002 Requestor J. SLOVE

Title CONSTRAINED LAYER II; LAYER OUT Machine ID RAYMOND

Actuator Rate .008"/SEC. = .40"/MIN.

Sketch of Test Set-Up: (note all relevant distances and angles)

Specimen#	Max Load	DATA FILE:	Specimen#	Max Load	DATA FILE:
sz. 36/34 1/2	FLAT HEAD		sz. 36	FULL HEAD	
#4.	243 41.6 lbs.	2439-1.TXT	#8.	40.5	2439-9.TXT
#5.	43.2	2439-2.TXT	#10.	41.0	2439-10.TXT
#12.	46.6	2439-3.TXT			
#13.	46.4	2439-4.TXT			
sz. 36/35	FLAT HEAD				
#6	43.5	2439-5.TXT			
#7	44.5	2439-6.TXT			
#14	49.3	2439-7.TXT			
#15.	46.0	2439-8.TXT			

Average: _____

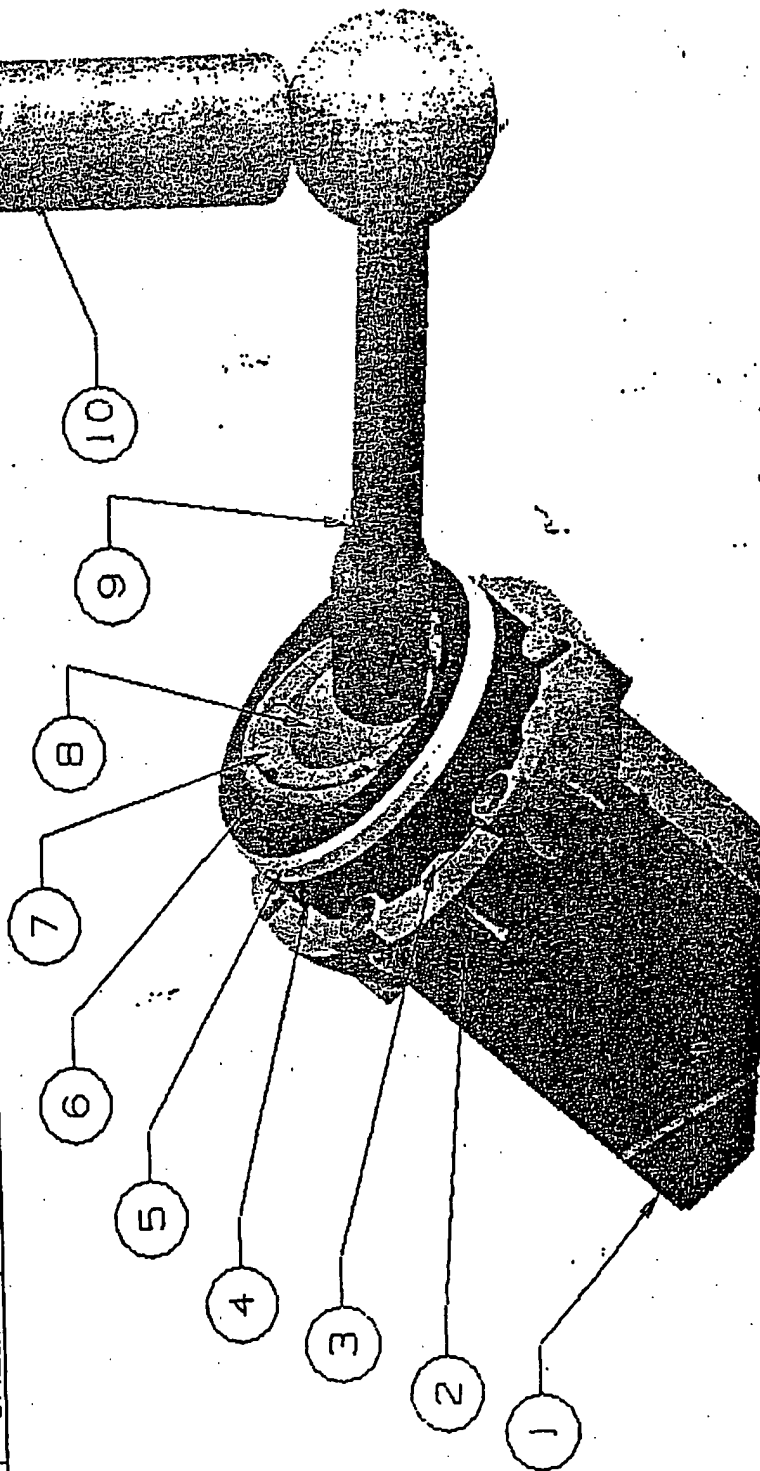
Average: _____

Notes: _____

Date Test Completed: 1-7-2002 Conducted by: K. HOWARD

Book# S-24 Continued on Page _____ Page 23

OBJECT NO.	COLOR	DESCRIPTION
1	GREEN	BASE FIXTURE
2	LT. BLUE	MODIFIED UNIVERSAL 58MM SHELL
3	YELLOW	SIZE 23 LOCKING RING
4	BLUE	TRI-POLAR LINER
5	YELLOW	REINFORCEMENT RING
6	GREEN	B1-POLAR LINER
7	RED	UHMWPE B1-POLAR INSERT
8	LT. BLUE	22MM STD. HEAD
9	LT. BLUE	TAPER TEST BAR
10	GREEN	PUSHING FIXTURE



HEAD Sz. 36/34 1/2 FLAT

LEVER-OUT

2439-1 41.6 lbs.

BIOMET ORTHOPEDICS, INC.

56 EAST BELL DRIVE
P.O. BOX 587 WARRSAU, IN 46581 USA

REF. INVESTIGATIONAL

INVESTIGATIONAL

RETURN TO GREG PORTER

#1 2439-1

LOT 815390

AFFIX TO PATIENT RECORDS

HEAD Sz. 36/35 FLAT

BIOMET ORTHOPEDICS, INC.

56 EAST BELL DRIVE
P.O. BOX 587 WARRSAU, IN 46581 USA

REF. INVESTIGATIONAL

INVESTIGATIONAL

RETURN TO GREG PORTER

#15.

2439-8 45.99 lbs.

LOT 815390

AFFIX TO PATIENT RECORDS

* FOOT RUN CAME OUT OF SWEET

HEAD Sz. 36/34 1/2 FLAT LEVER-OUT

BIOMET ORTHOPEDICS, INC.

56 EAST BELL DRIVE
P.O. BOX 587 WARRSAU, IN 46581 USA

REF. INVESTIGATIONAL

INVESTIGATIONAL

RETURN TO GREG PORTER

#5. 2439-2 43.2 lbs.

LOT 815390

AFFIX TO PATIENT RECORDS

HEAD Sz. 36/36

BIOMET ORTHOPEDICS, INC.

56 EAST BELL DRIVE
P.O. BOX 587 WARRSAU, IN 46581 USA

REF. INVESTIGATIONAL

INVESTIGATIONAL

RETURN TO GREG PORTER

#8.

2439-9 40.5 lbs.

LOT 815390

AFFIX TO PATIENT RECORDS

HEAD Sz. 36/34 1/2 FLAT

BIOMET ORTHOPEDICS, INC.

56 EAST BELL DRIVE
P.O. BOX 587 WARRSAU, IN 46581 USA

REF. INVESTIGATIONAL

INVESTIGATIONAL

RETURN TO GREG PORTER

#12 2439-3 46.6 lbs.

LOT 815390

AFFIX TO PATIENT RECORDS

HEAD Sz. 36/36

BIOMET ORTHOPEDICS, INC.

56 EAST BELL DRIVE
P.O. BOX 587 WARRSAU, IN 46581 USA

REF. INVESTIGATIONAL

INVESTIGATIONAL

RETURN TO GREG PORTER

#16.

2439-10 41.0 lbs.

LOT 815390

AFFIX TO PATIENT RECORDS

HEAD Sz. 36/34 1/2

LEVER OUT

BIOMET ORTHOPEDICS, INC.

56 EAST BELL DRIVE
P.O. BOX 587 WARRSAU, IN 46581 USA

REF. INVESTIGATIONAL

INVESTIGATIONAL

RETURN TO GREG PORTER

#13. 2439-4 46.4 lbs.

LOT 815390

AFFIX TO PATIENT RECORDS

HEAD Sz. 36/35 FLAT

LEVER OUT

BIOMET ORTHOPEDICS, INC.

56 EAST BELL DRIVE
P.O. BOX 587 WARRSAU, IN 46581 USA

REF. INVESTIGATIONAL

INVESTIGATIONAL

RETURN TO GREG PORTER

#6. 2439-5 43.5 lbs.

LOT 815390

AFFIX TO PATIENT RECORDS

BIOMET ORTHOPEDICS, INC.

56 EAST BELL DRIVE
P.O. BOX 587 WARRSAU, IN 46581 USA

REF. INVESTIGATIONAL

INVESTIGATIONAL

RETURN TO GREG PORTER

#7. 2439-6 44.5.

LOT 815390

AFFIX TO PATIENT RECORDS

HEAD Sz. 36/35 FLAT

BIOMET ORTHOPEDICS, INC.

56 EAST BELL DRIVE
P.O. BOX 587 WARRSAU, IN 46581 USA

REF. INVESTIGATIONAL

INVESTIGATIONAL

RETURN TO GREG PORTER

#14. 2439-7 49.3 lbs.

LOT 815390

AFFIX TO PATIENT RECORDS

HEAD Sz. 36/35 FLAT
LEVER OUT.

Test Report MT-2439
Lever-Out with 3 different 36mm Co-Cr Modular Heads

Test Site:

Biomet Inc.
Airport Industrial Park
Warsaw, IN 46580

Conducted By:

Jason Slone
Kelly Howard

Development Engineer
Laboratory Technician/Supervisor

Jason Slone 12/11/2002

Dates Conducted:

January 7, 2002

Objective:

Determine the amount of torque required to lever-out three different 36.0 mm modular head designs from the liner, as well as determining how much if any a Cobalt Reinforcement ring will strengthen design from a Titanium Reinforcement Ring.

Materials:

Part Name	Part Number	Lot Number	Size	Quantity
23 Constrained +5 Liner w/Cobalt Ring	Investigational	815390	23	6
23 Constrained +5 Liner w/Ti-6Al-4V Ring	Investigational	815390.	23	6
CoCr Reinforcement Ring	Investigational	R&D	23	6
Ti-6Al-4V Reinforcement Ring	Investigational	R&D	23	6
36mm Full Sphere Modular Head	Investigational	R&D	36	1
36mm/35 flat Full Sphere Modular Head	Investigational	R&D	36/35	1
36mm/34.5 flat Full Sphere Modular Head	Investigational	R&D	36/34.5	1

The 23 Constrained Liners were manufactured complete at Biomet Warsaw. The Retaining Rings and Modular Head were manufactured at Biomet Warsaw in the Research and Development area. The rings were manufactured complete except for chemical etch, sterilization and packaging processes, which have no effect of this test.

Methods:

See Attached Sheet for Test Procedure

Calculations:

Lever-Arm:

The calculated lever-arm for this test was done using the CAD system. See Attached Figures with Sample Numbers. The constrained liner design was taken and rotated until the lever-out bar was horizontal. Then the head was constrained so that it must pop out of the liner perpendicular to the face of that liner. The maximum displacement was then used to determine where the Force from the actuator was being placed.

Percent Increase of CoCr Reinforcement Ring:

$$[(\text{Average Torque Ti-6Al-4V}) - (\text{Average Torque CoCr})] / (\text{Average Torque Ti-6Al-4V})$$

Results:

The results of the lever out test were as follows.

Mechanical Test 2439					
Specimen #	Maximum Displacement (in)	Maximum Recorded Force (lbs)	Calculated Lever Arm (in)	Calculated Torque (in-lbs)	Modular Head Size
4	0.652	41.6	3.216	133.8	36/34.5
5	0.662	43.2	3.215	138.9	
12	0.666	46.5	3.215	149.5	
13	0.749	46.4	3.206	148.9	
6	0.687	43.5	3.213	139.8	36/35.0
7	0.746	44.5	3.206	142.7	
14	0.690	49.8	3.213	158.4	
15	0.680	46.9	3.213	147.8	
8	0.720	40.5	3.209	130.0	36/36
16	0.693	42.4	3.211	122.7	

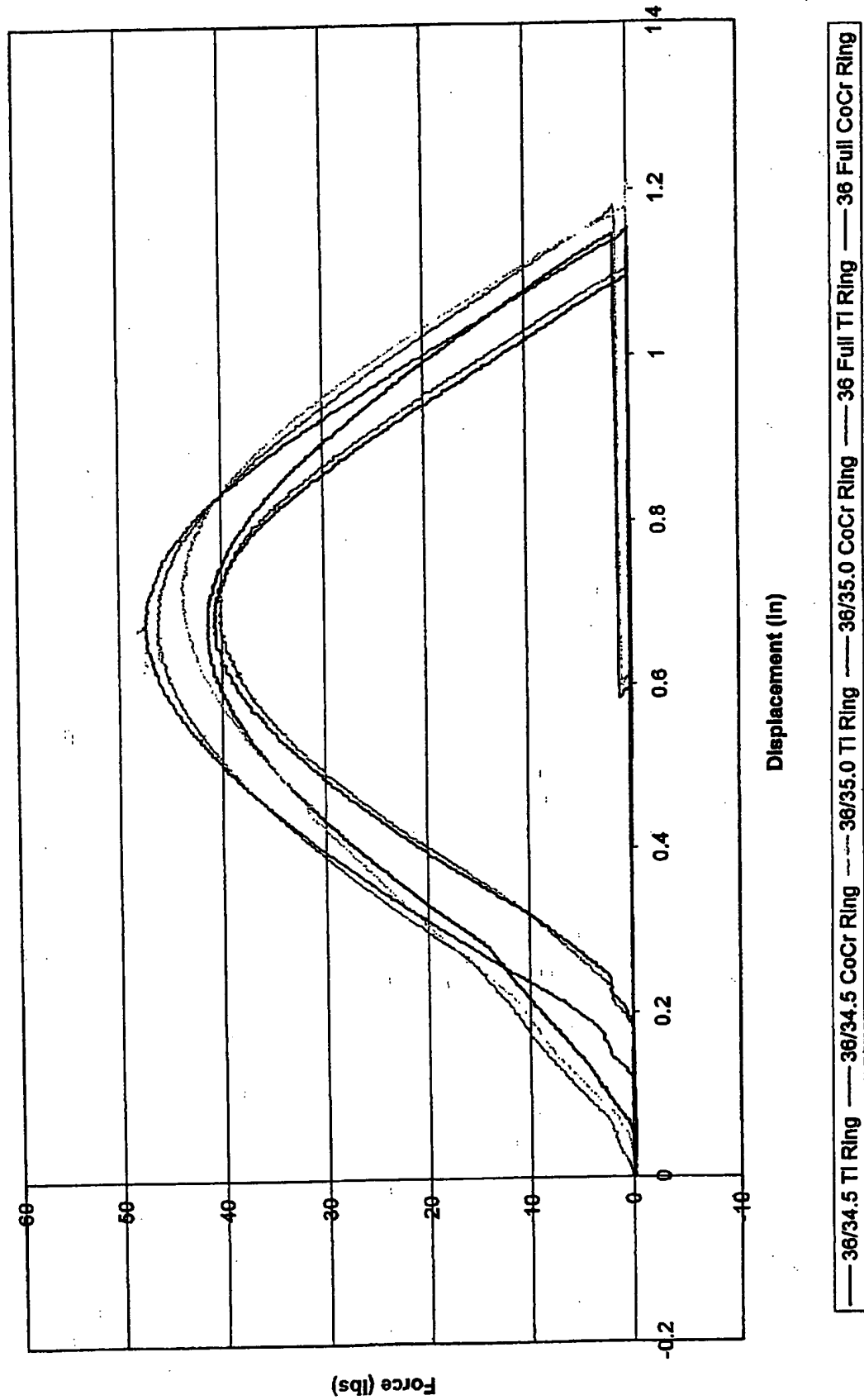
Note: Blocks in Gray are Liners with a Cobalt Chrome Reinforcement Ring;
Bold Numbers are maximum Torque

Conclusion:

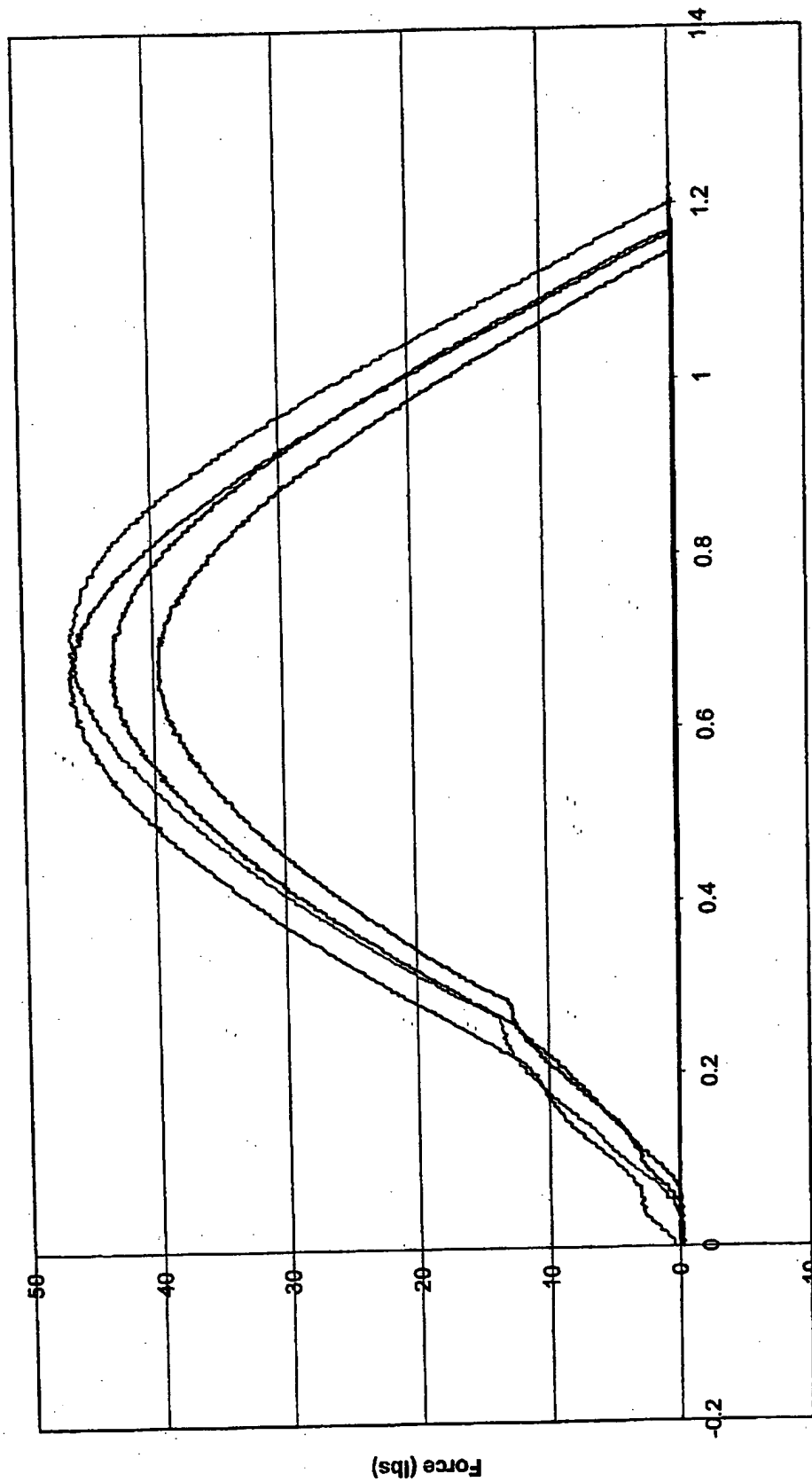
As can be seen from the data the maximum amount of torque is acquired using a CoCr Reinforcement Ring with a 36/35.0 modular head. This scenario makes sense because it will displace a small amount of polyethylene when placed into the liner, but maintain the most amount of surface area when in a lever-out position. See tests reports MT2239 and MT2412 showing what the difference can be when using a full spherical head compared to a head that is not a complete sphere.

The 36/35.0 modular head shows the best results with either the CoCr or Ti-6Al-4V Reinforcement Rings. The CoCr Reinforcement Ring increases the leverout strength of this UHMWPE constrained liner design by roughly 9%.

Average Force vs. Displacement



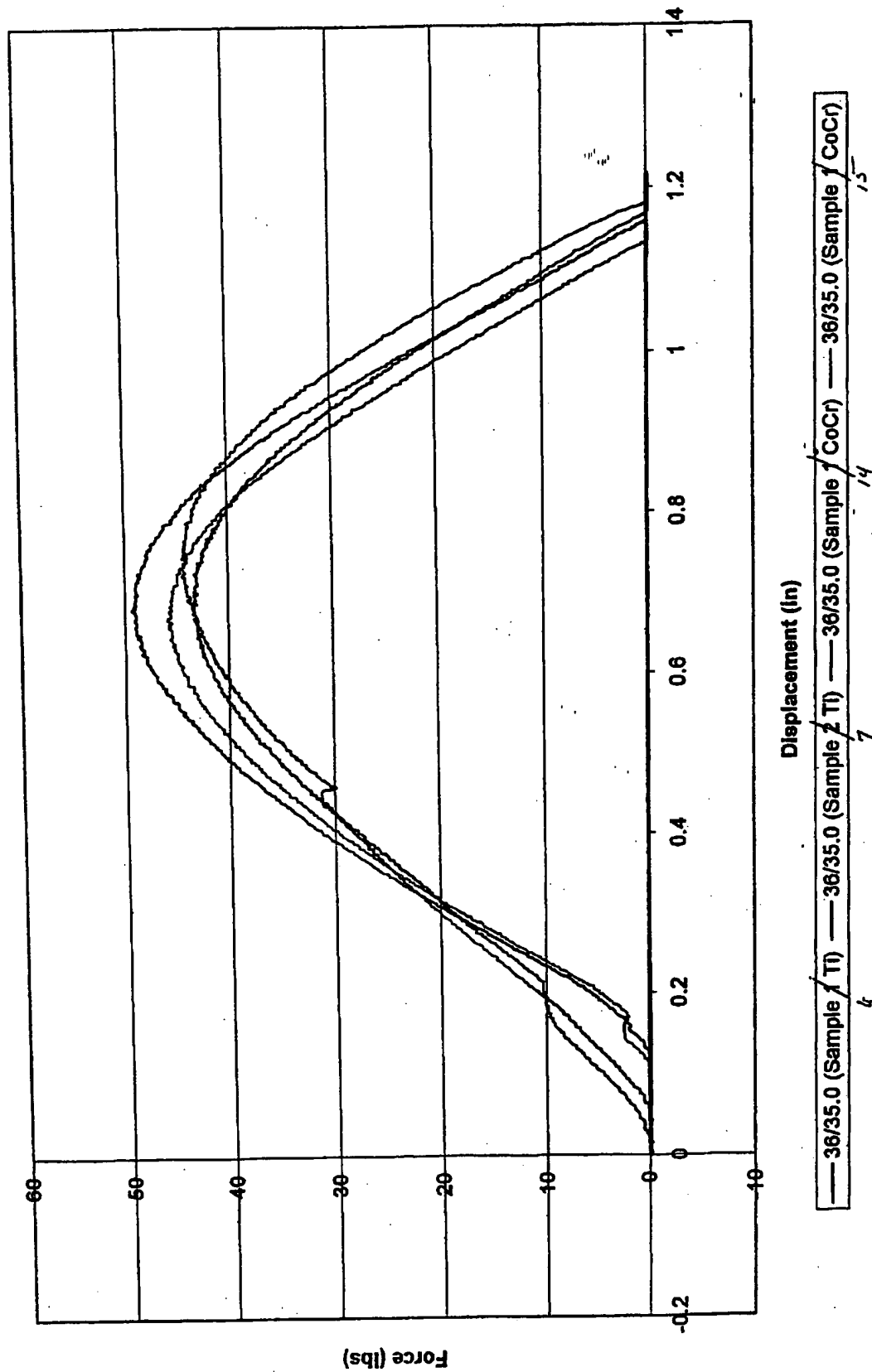
Force vs. Displacement



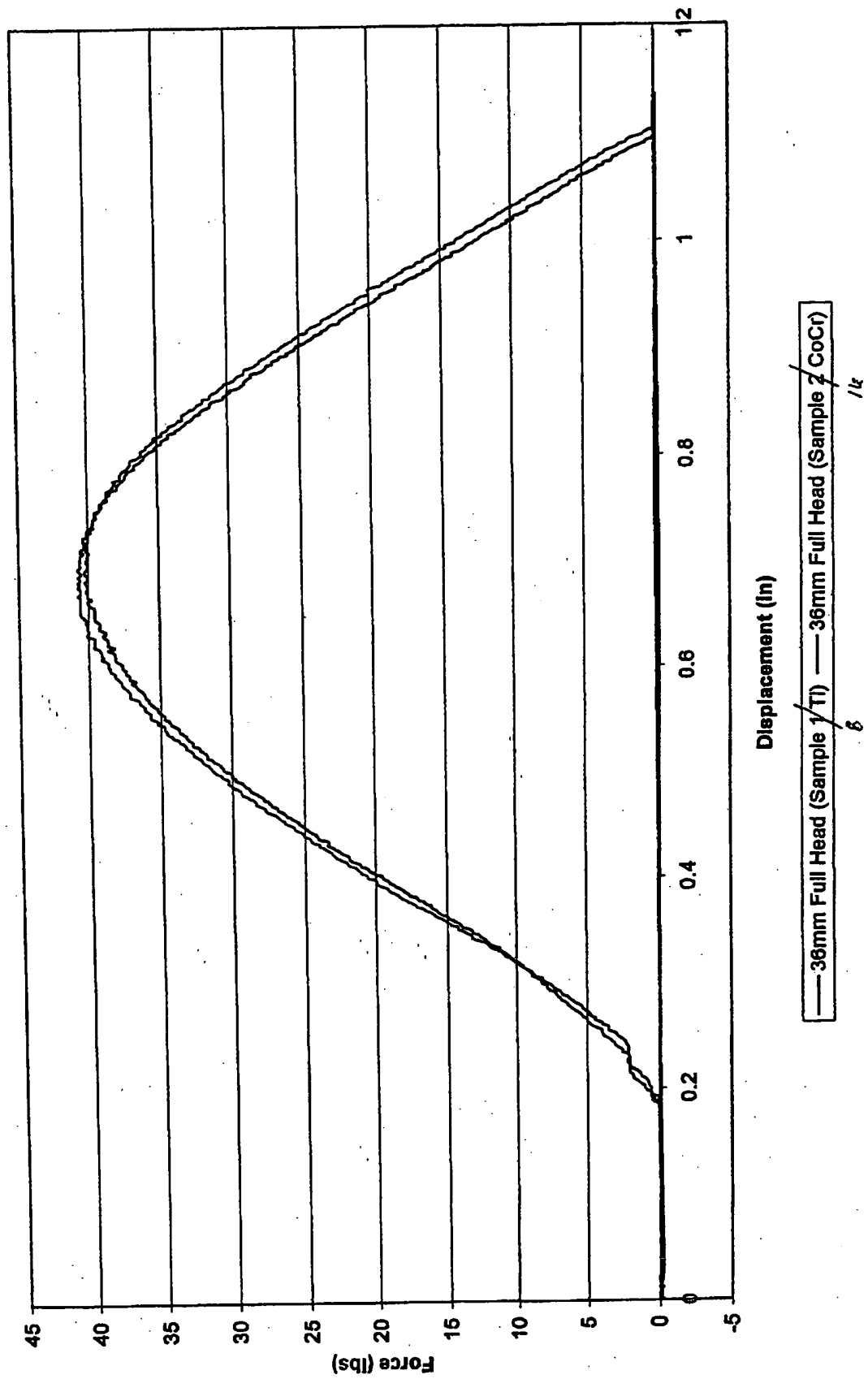
4
5
13

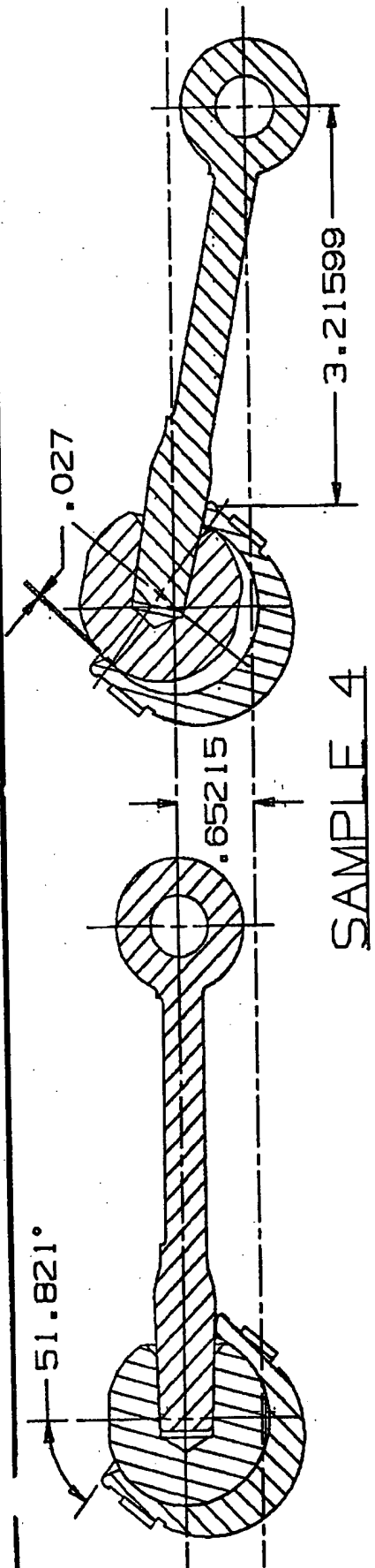
— 36/34.5 (Sample 1 Ti) — 36/34.5 (Sample 2 Ti) — 36/34.5 (Sample 2 CoCr)

Force vs. Displacement

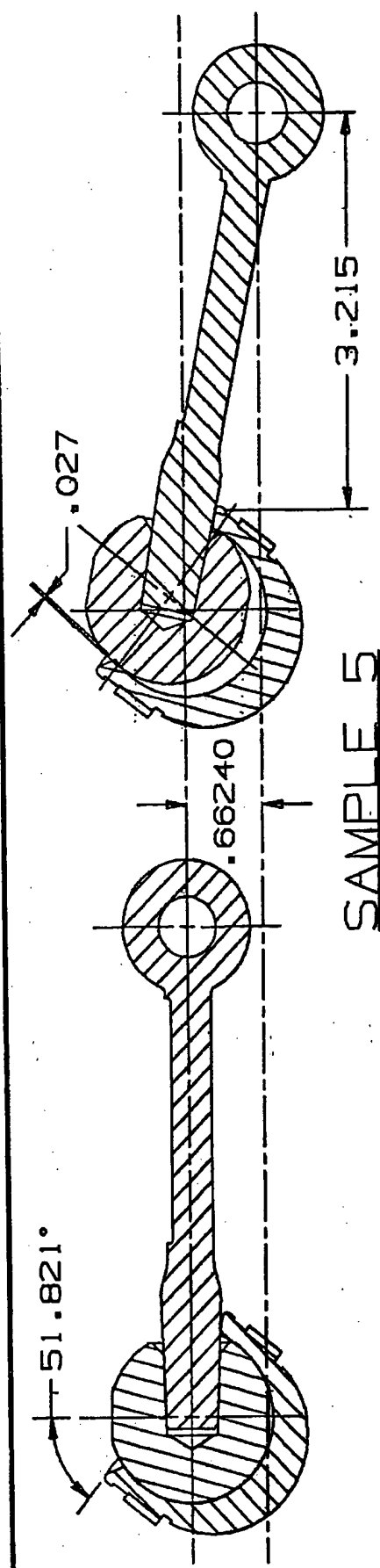


Force vs. Displacement

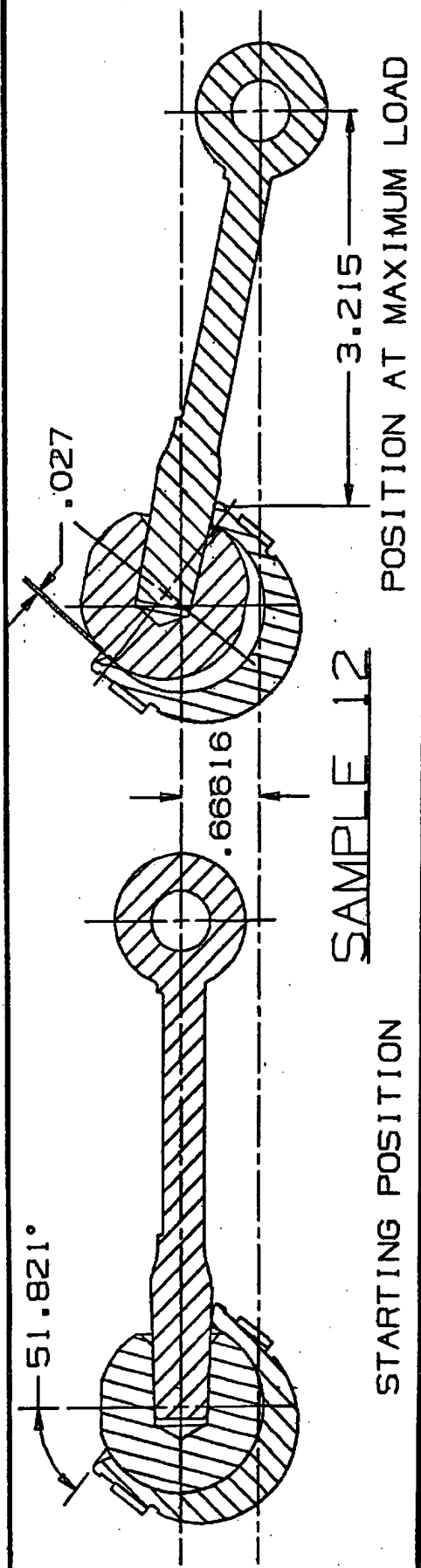




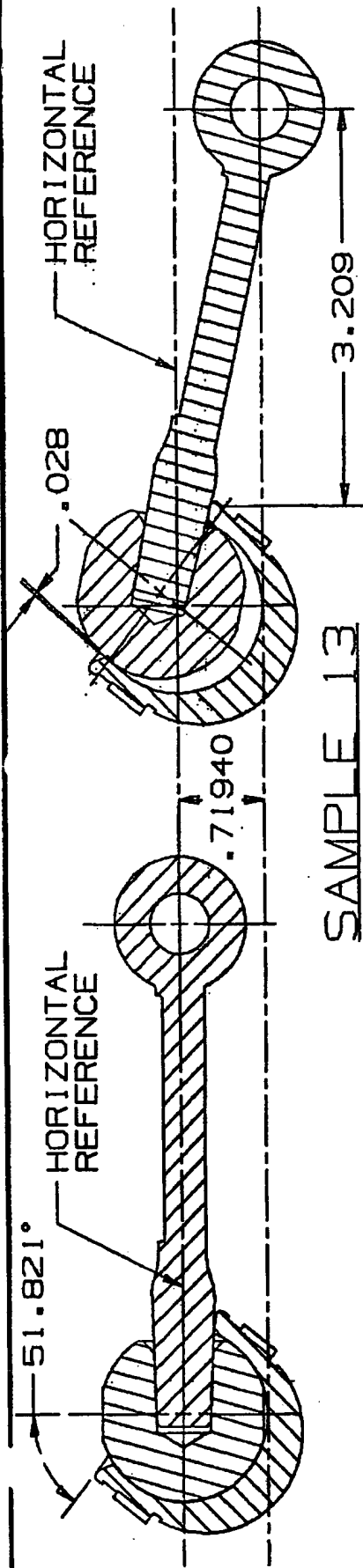
SAMPLE 4



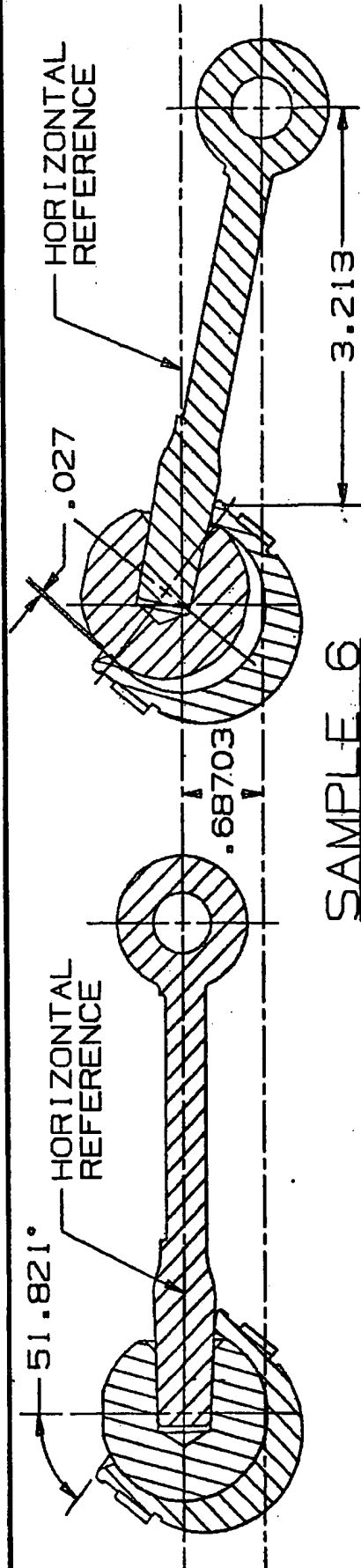
SAMPLE 5



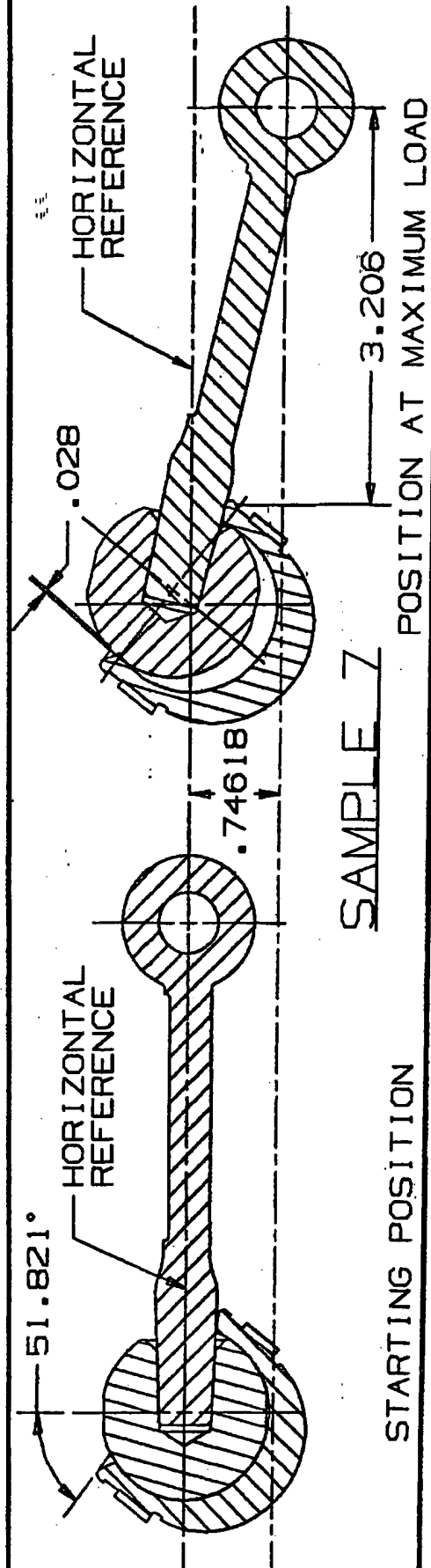
SAMPLE 12



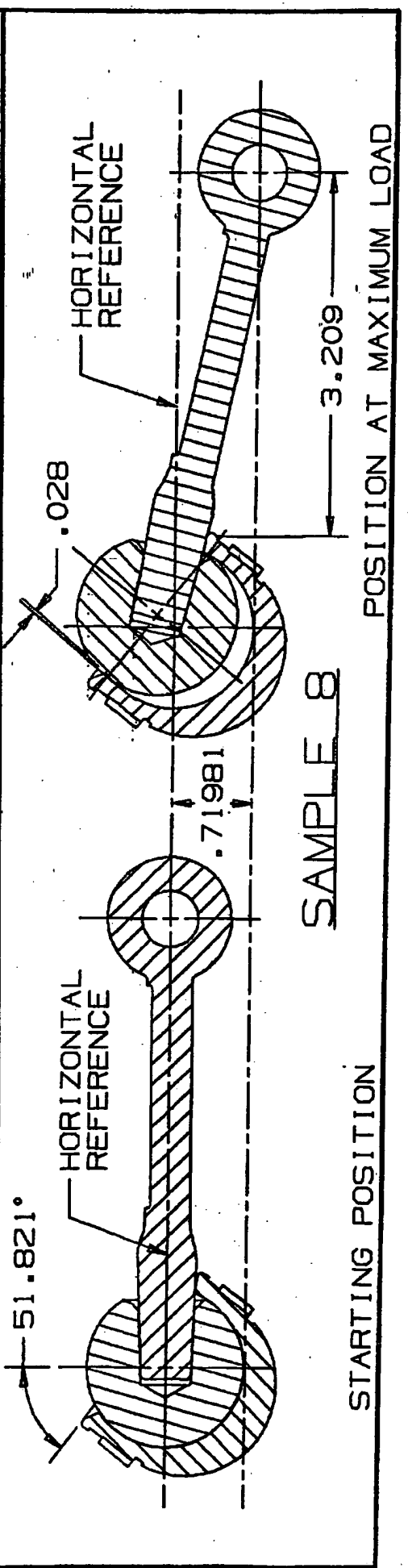
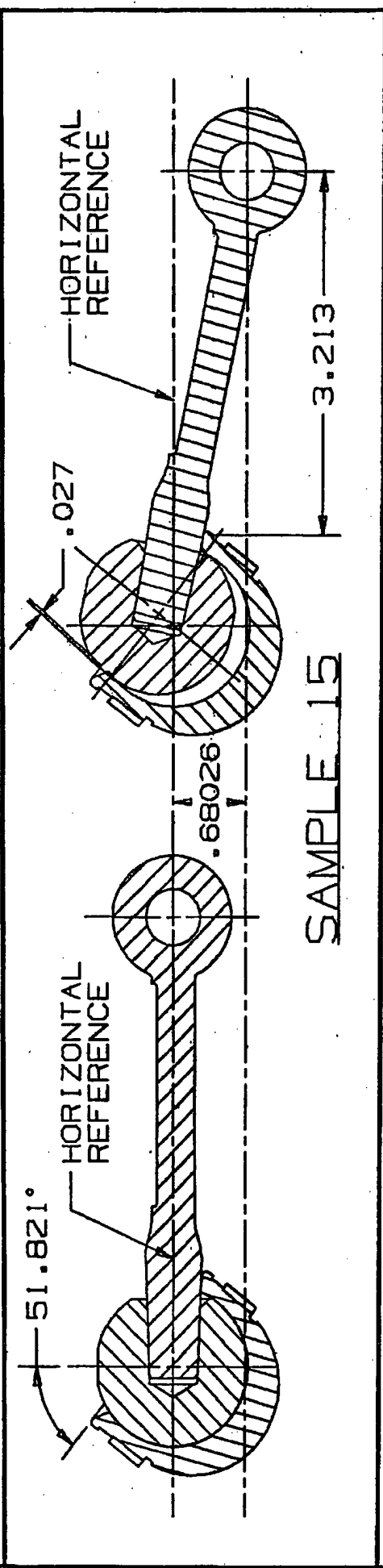
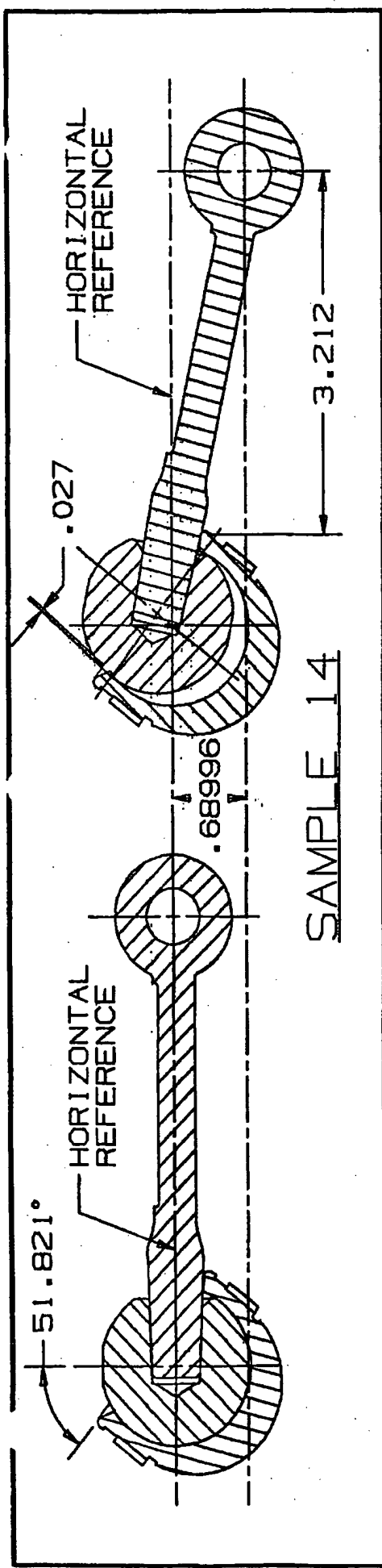
SAMPLE 13

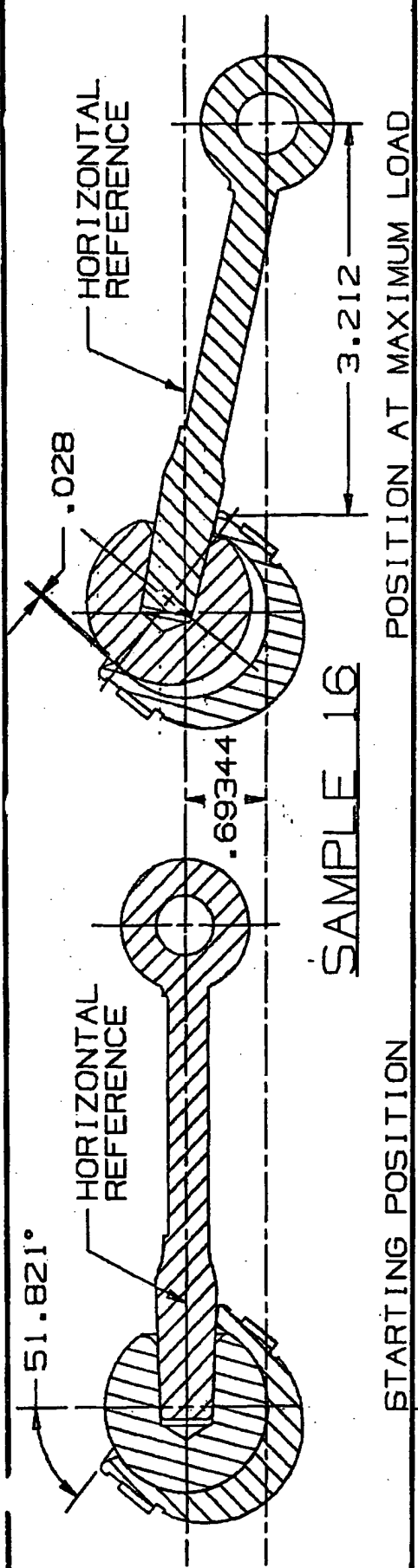


SAMPLE 6



SAMPLE 7





36mm Constrained Liners								
Specimen #	Initial I.D. Dimension	I.D. after Liq.N	Initial O.D. Dimension	O.D. after Liq.N	Initial O.D. Ring Groove	O.D. Ring Groove after Liq.N	Ring I.D.	Ring Material
1	0.71722	0.71907	0.83100	0.83123	1.5770	1.5775	1.6900	TL-6Al-4V
2	0.71775	0.71532	0.82629	0.82687	1.5730	1.5725	1.6890	TL-6Al-4V
3	0.71743	0.71566	0.82311	0.82332	1.5700	1.5715	1.6890	TL-6Al-4V
4	0.71764	0.71546	0.82649	0.82677	1.5730	1.5730	1.6895	TL-6Al-4V
5	0.71616	0.71731	0.82677	0.82779	1.5740	1.5750	1.6890	TL-6Al-4V
6	0.71789	0.71442	0.82350	0.82361	1.5710	1.5695	1.6895	TL-6Al-4V
7	0.71639	0.71787	0.82588	0.82701	1.5720	1.5730	1.6890	TL-6Al-4V
8	0.71789	0.71590	0.82631	0.82686	1.5720	1.5725	1.6890	TL-6Al-4V
9	0.71708	0.71638	0.82585	0.82624	1.5720	1.5720	1.6870	Co-Cr
10	0.71763	0.71792	0.82627	0.82669	1.5730	1.5735	1.6890	Co-Cr
11	0.71781	0.71888	0.82613	0.82691	1.5730	1.5785	1.6870	Co-Cr
12	0.7163	0.71701	0.82508	0.82619	1.5750	1.5730	1.6880	Co-Cr
13	0.71714	0.69682	0.82681	0.82805	1.5750	1.5760	1.6880	Co-Cr
14	0.7159	0.71719	0.82617	0.82785	1.5730	1.5740	1.6870	Co-Cr
15	0.71638	0.71824	0.82548	0.82641	1.5720	1.5725	1.6885	Co-Cr
16	0.71708	0.71752	0.82550	0.82605	1.5750	1.5760	1.6890	Co-Cr
17	0.71765	0.71917	0.82868	0.82863	1.5750	1.5750	1.6890	Co-Cr
18	0.71688	0.71789	0.82553	0.83822	1.5750	1.5755	1.6890	Co-Cr
19	0.71807	0.71841	0.82865	0.82875	1.5730	1.5750	1.6890	Co-Cr
20	0.71748	0.71839	0.82678	0.82733	1.5720	1.5730	1.6890	Co-Cr

NOT Put in Liquid Nitrogen		
Specimen #	Difference	Difference
1	-0.0019	-0.0005
2	0.0024	0.0005
3	0.0018	-0.0015
4	0.0022	0.0000
5	-0.0011	-0.0010
6	0.0035	0.0015
7	-0.0015	-0.0010
8	0.0020	-0.0005
9	0.0007	0.0000
10	-0.0003	-0.0005
11	0.0011	-0.0035
12	-0.0007	0.0020
13	0.0203	-0.0010
14	-0.0013	-0.0010
15	-0.0019	-0.0005
16	-0.0004	-0.0010
17	-0.0015	0.0000
18	-0.0010	-0.0005
19	-0.0003	-0.0020
20	-0.0009	-0.0010

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